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**Attorney Docket No. 10517-700.US0**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appl. No.	:	10/523,857	Confirmation No.:	7154
Applicant	:	Ross E. MANTLE		
Filing Date	:	May 11, 2005		
Title	:	Device for the Extravascular Recirculation of Liquid in Body Cavities		
Group Art Unit	:	3761		
Examiner	:	Philip R. WIEST		
Docket No.	:	10517-700.US0		
Customer No.	:	66854		

**APPELLANT'S REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41**

MailStop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Sir:

Appellant submits this brief in accordance with the provisions of 37 C.F.R. § 41.41 in response to the Examiner's Answer mailed July 25, 2008. This Reply Brief is therefore timely filed.

Please charge any fees, if any, for this filing to Deposit Account No. 50-4050.

## **RESPONSE TO ARGUMENTS**

This Reply Brief responds to the Examiner's Answer mailed July 25, 2008.

The Examiner's explanation of the basis of his rejection mischaracterizes the prior art. In addition, the Examiner's analysis under 35 U.S.C. § 103(a) is erroneous under *KSR* and other controlling precedent. Appellant addresses the implications of these errors with respect to each independent claim below.

### **A. Claim 1**

The basis stated in the Examiner's Answer for the rejection of claim 1 over Osterholm, Leonard and Ginsburg under § 103(a) mischaracterizes these references and misapplies the law. For the reasons stated below and in the Appeal Brief, claims 1-13 are patentable over Osterholm, Leonard, Ginsburg and the other prior art of record.

#### **1. Osterholm and Leonard**

Claim 1 recites a first pump means for infusing liquid into a cavity, means for monitoring temperature within the cavity, means for monitoring pressure within the cavity, and a second pump means for withdrawing liquid from the cavity. The Examiner admits that Osterholm does not disclose the recited second pump and relies on Leonard to demonstrate the obviousness of adding that element to the Osterholm system. (Ex. Ans., p. 4). In doing so, however, the Examiner mischaracterizes Leonard's disclosure.

As Appellant indicated in the Appeal Brief, Leonard does not infuse and withdraw fluid from the same cavity. Rather, Leonard removes venous blood from a vein and returns oxygenated blood to an artery, which is a completely different anatomical space than the space from which the blood was removed. In refuting this statement, the Examiner asserts that "arteries and veins are part of the same circulatory system. When blood is withdrawn from [Leonard's] first pump, the blood pressure in the body will drop unless blood is reinfused through the second pump." (Ex. Ans., p. 11). This argument by the Examiner—for which the Examiner provides no supporting citations whatsoever—mischaracterizes Leonard's disclosure and shows a profound lack of knowledge of basic anatomy. In fact, while arteries and veins may all be part of the circulatory system and may all be contained within the same body, arteries and veins are separated by capillaries and do not form a "cavity" as recited in claim 1. Moreover, the

Examiner's contention that changes in blood pressure within a vein will affect blood pressure in an artery, or vice versa, is simply wrong.

Furthermore, the Examiner never addresses the limitation in claim 1 that the recited cavity is outside of a blood vessel. Leonard, on the other hand, withdraws and infuses blood to blood vessels only. (See Leonard Fig. 1). The Examiner states no legal basis for a construction of the claim that ignores this claim limitation.

Finally, in concluding his analysis of Leonard, the Examiner asserts that "it would have been obvious . . . to combine the apparatus of Osterholm with the plurality of pumps of Leonard so that the flow rate of fluid into and out of the cavity may be controlled, thereby regulating the pressure within the cavity." (Ex. Ans., pp. 4 and 12). In addition to being factually incorrect, the Examiner's obviousness analysis merely points to a presumed result of the combination and completely omits any reasonable rationale for combining the features of these two references. Instead, the Examiner merely uses the roadmap provided by Appellant's disclosure, which is the essence of impermissible hindsight. The Examiner has therefore failed to state a *prima facie* basis for the obviousness of the combination of Osterholm and Leonard.

## 2. Osterholm and Ginsburg

The Examiner also admits that Osterholm lacks the recited means for measuring temperature and pressure within the cavity to which the first pump infuses liquid and from which the second pump withdraws liquid. (Ex. Ans., pp. 4-5). The Examiner's reliance on Ginsburg to show the obviousness of those features is both factually and legally incorrect.

Ginsburg's heat exchange catheter system is inserted into a blood vessel to heat or cool blood flowing to another part of the body, such as the brain. (See Ginsburg Col. 9, lines 3-25). The heat exchanger liquid is never infused into or withdrawn from the blood vessel or from any body cavity. As stated above with respect to Leonard, the Examiner never addresses the limitation in claim 1 that the cavity is outside of a blood vessel. Furthermore, any temperature or pressure monitoring in Ginsburg's system takes place in an anatomical location far removed from the blood vessel into which the heat exchange catheter is inserted, a difference between claim 1 and Ginsburg's disclosure that the Examiner did not acknowledge. Thus, Ginsburg cannot possibly add what Osterholm lacks with respect to the subject matter of claim 1.

The Examiner's legal analysis is faulty as well. The Examiner contends that "it would have been obvious . . . to combine the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly." (Ex. Ans., p. 5). The Examiner also states that "temperature measurements will be more accurate inside the body than in a fluid reservoir" and that "taking internal pressure measurements allows the pressure within the cavity to be controlled." (Ex. Ans., p. 5). These observations by the Examiner, however, merely state the Examiner's presumed result of the addition of certain features of Ginsburg with the Osterholm system, using Appellant's disclosure as his guide. Apart from restating Appellant's disclosure, the Examiner has not provided any reasonable rationale for adding such monitoring means to the Osterholm system and has therefore not provided a *prima facie* basis for the obviousness of the combination of Osterholm and Ginsburg.

For at least these reasons, claim 1 is patentable over Osterholm, Leonard and Ginsburg under § 103(a), and the Examiner's rejection of claims 1-13 should be overturned.

## **B. Claim 18**

As stated in the Appeal Brief, the Final Rejection never addressed certain key limitations of claim 18 and does not reference Leonard or Ginsburg at all. The Examiner's Answer states for the first time the Examiner's rationale for the rejection of claim 18 over Osterholm, Leonard and Ginsburg under § 103(a). Once again, however, the Examiner's rationale mischaracterizes these references and misapplies the law. For the reasons stated below and in the Appeal Brief, claims 18-27 are patentable over Osterholm, Leonard, Ginsburg and the other prior art of record.

### **1. Osterholm and Ginsburg**

Claim 18 recites a catheter configured for insertion into a cavity (outside of blood vessels) and introduction and removal of liquid from the cavity. The Examiner contends that "Osterholm clearly teaches a catheter (i.e. fluid flow line) that is adapted to introduce and remove fluid from the cavity." (Ex. Ans., p. 13). In fact, however, Osterholm introduces fluid into a lateral ventricle 20 of the brain through injection cannula 20a and removes fluid from a portion of the brain remote from the injection location, such as the subarachnoid space, using an

entirely different fluid line. (See Osterholm Fig. 1 and Col. 11, lines 22-35). The Examiner's rejection mischaracterizes Osterholm's disclosure and fails to indicate how each and every element of claim 18 is shown in the prior art.

Furthermore, the Examiner states that "it would have been obvious . . . to modify the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to provide alternate means for accurately monitoring the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly." (Ex. Ans., p. 13). Once again, apart from restating Appellant's disclosure, the Examiner has not provided any reasonable rationale for adding these monitoring means to the Osterholm system and has therefore not provided a *prima facie* basis for the obviousness of the combination of Osterholm and Ginsburg.

## 2. Osterholm and Leonard

While the Examiner rejected claim 18 over Osterholm, Leonard and Ginsburg in the Final Office Action, and while the Examiner restated this basis of his rejection in the Examiner's Answer, the Examiner has still never explained how he is applying Leonard in his rejection. The Examiner has failed to state a *prima facie* basis for the rejection of claim 18 under § 103(a). Claim 18 is therefore patentable over Osterholm, Leonard and Ginsburg under § 103(a), and the Examiner's rejection of claims 18-27 should be overturned.

## **C. Claim 28**

The Examiner's Answer does not specifically address the elements of independent claim 28. Instead, the Examiner points to his arguments in support of the rejection of claim 18. (Ex. Ans., pp. 12-13). Claim 28 and claim 18 are of different scope, however, and the Examiner bears the burden of establishing a *prima facie* basis for the obviousness rejection of claim 28. As Appellant stated in the Appeal Brief, the Examiner did not state the basis of his rejection of claim 28 in the Final Office Action. The Examiner did not remedy that failure in the Examiner's Answer. The Examiner has not established a *prima facie* basis for the obviousness of claim 28. Claim 28, and claims 29-31 depending from it, are patentable over the prior art of record under § 103(a), and the Examiner's rejection of those claims should be overturned.

#### **D. Claim 32**

It appears that the Examiner mistakenly referred to apparatus claims 28-30 when intending to discuss the rejection of method claims 32-37. (Ex. Ans., p. 14.) As with claim 28, the Examiner never specifically addresses the key elements of method claim 32 in either the Final Office Action or in the Examiner's Answer. The Examiner has therefore failed to establish a *prima facie* basis for the obviousness of claim 32. Claim 32, and claims 33-37 depending from it, are patentable over the prior art of record under § 103(a), and the Examiner's rejection of those claims should be overturned.

#### **CONCLUSION**

For the reasons stated above and in the Appeal Brief, claims 1-13 and 18-37 are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. § 103 are improper and should be overturned. Appellant respectfully asks the Board to overturn the Examiner's rejection with instructions to allow the claims.

Respectfully submitted,

Date: September 25, 2008

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